O4

Improve Review Efficiency

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O4 (Activity 1)	Improve the efficiency of the enforcement action review process.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Timeliness and quality of EIRs
Scope and nature of the process to be followed.[2]	A. QSIT trained Compliance officers, one each from DEN-DO, LOS-DO and MIN-DO, who participated in the QSIT Study, will be asked to complete and provide comments to the attached survey. Survey to issue by 1/29/99 Survey target completion date 2/12/99 Analysis to follow B. The replies to question #6 of the Compliance Officer QSIT Evaluation Form, that is being used during th QSIT Study, will be tabulated. Overall responsibility for this activity: S. Niedelman (HFZ-330)	
Acceptance criteria (if known)	An improvement in efficiency of regulatory action processing	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity adequately assesses the work accomplished to date. It is limited by the size and scop of the number of firms in the pilot and the limited number of trained compliance officers involved.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	It summarily represents the experience of the inspectional and compliance personnel who have been included in the QSIT pilot.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O4	Improve the efficiency of the enforcement action review process.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Timeliness and quality of EIRs
Acceptance Criteria	An improvement in efficiency of regulatory action processing.	
Summary of Results	A. Worksheet Results attached. B. Compilation of Question 6 from QSIT Evaluation form attached.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	Additional comments are included in each attachment.	
Activity Champion(s)	Steven Niedelman	

Quality System Inspection Technique (QSIT) Pilot

Compliance Officer Evaluation Form

1. Did the QSIT approach generally result in an EIR which was better organized and easier to review and evaluate?

   5 4 3 2 1 0
   (strongly agree) (do not agree)

2. Did the QSIT approach result in an EIR of generally higher quality?

   5 4 3 2 1 0

3. Did the QSIT approach result in more thorough documentation of violations?

   5 4 3 2 1 0

4. Did QSIT facilitate the preparation of regulatory action recommendations?

   5 4 3 2 1 0

5. Did QSIT affect the time needed to review the EIR?

   5 3 2 1 0
   (much quicker) (much longer) (none)

6. Did QSIT affect the time needed to prepare a regulatory recommendation?

   5 4 3 2 1 0
   (much quicker) (much longer) (N/A)

7. If QSIT had an affect on the quality of a regulatory action (or recommendation), that affect can best be described as:

   5 4 3 2 1 0
   (very positive) (negative) (none)

Please include any comments on your experience with QSIT and its effect on the review and preparation of regulatory actions or recommendations, or any other comments that you may have on QSIT below:

_____

_____

_____

_____

_____

_____

Quality System Inspection Technique (QSIT) Pilot

Attachment A. **Results of Compliance Officers Survey Form**

Footnote: Due to the small number of replies, it would not be accurate to "average the responses" to several questions, for some were not applicable, and averaging the results would negatively bias the outcome (because the numerical value "0" – represents not applicable!) The replies to each of these questions are described below.

Question 4. Actual replies were: 5(1), 2(2), and NA (3);
Question 6. Actual replies were: 5(1), 3(2), and 0(3);
Question 7. Actual replies were: 4(1), 3(3), and 0(3)

Comments:

(1) "I really liked the QSIT process because I didn't get extraneous information. As in all things, a lot depends on CSO technique – some are still way too wordy, some were too skimpy and had to be rewritten."

(2) "QSIT aids in the review for regulatory action. I didn't see much gain in preparation of the regulatory action itself. The organization of the subsystems in the EIR facilitated review."

(3) "QSIT assisted in moving to the justification for proceeding with the desired action. The handbook provided sufficient reassurance that all salient points were covered by regulation."

Quality System Inspection Technique (QSIT) Pilot

Attachment B. Tabulation of Question 6 – Compliance Officer Evaluation Form

Question 6. Did the investigator's focus on key areas help make your review easier?

Total number of forms submitted: 41 (15(1), 12(2) and 14(3))
Number of forms used for accounting: 39 (1, no reply (3); (1, both "Yes" and "No" checked off)
Tabulation of Responses: Yes: 37 (94.9%)
No: 2 (5.1%)

Comments:

District 1

- "Focused on system"
- "Helped concentrate on system"
- "Focused on violative areas that were significant"
- "Made it clear it was NAI"
- "Although it was pretty clear it was NAI"
- "Much easier"
- "As far as 483- focused on problems in validation, following procedures, complaints"
- "483 was focused on key areas."

District 2

- "Used subsystem headings on 483 and EIR – made review easier and Part V easy to apply"
- "There were no individual headings made under which each key area was reported. Having them would have expedited review."
- "Would be nice to make reporting structure uniform (require headings for each subsystem in EIR) to speed review."

District 3

- "Most definitely! Eliminates a lot of irrelevant materials. Traditionally I would look at Discussion with Management, Objectionable Conditions and Supporting Documentation to make decision."
- "Still a tendency to use essential elements of proof to formulate decision"
- "Especially in management controls"

Note: Numbers appearing in parentheses refer to the study number assigned to the reporting district.

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O4 (Activity 2)	Improve the efficiency of the enforcement action review process.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by Compliance Officers to a multi-part question on an Evaluation Form
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Each QSIT Study EI documentation is to be reviewed by QSIT trained compliance officers. There will be one compliance officer from each of the Study districts. The compliance officers will classify each EIR using QSIT Study draft Compliance Program 7382.830 Part V guidance. The compliance officers will complete an Evaluation Form for each of their reviews. They will be asked to provide their views on the QSIT Part V, and also on QSIT aspects which were designed to make the enforcement action review process more efficient. The effect of QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) on the review process for inspections classified OAI using the QSIT Part V will be determined by the following multi-part Evaluation Form question: "Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) useful during your review? Yes __No __ If yes, which tools were most useful and how wer they helpful?" Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the QSIT tools were useful during reviews of inspections classified OA using the QSIT Part V.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct and objective measurement of whether the QSIT tools were useful during the review process. It provides an indirect measurement of the effect on the efficiency of the process.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows compliance offic (internal stakeholders) to express their views concerning the effect of QSIT on the performance of their duties.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O4	Improve the efficiency of the enforcement action review process.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
2	Test	Responses by Compliance Officers to a multi-part question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the QSIT tools were useful during reviews of inspections classified OAI using the QSIT Part V.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. QSIT Study EI documentation was reviewed by QSIT trained compliance officers (one from each of the Study Districts). The compliance officers classified the EIRs using QSIT Study draft Compliance Program 7382.830 Part V guidance. The compliance officers completed Evaluation Forms for their reviews. They provided their views on the QSIT Part V, and also on QSIT aspects which were designed to make the enforcement action review process more efficient. The effect of QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) on the review process for inspections classified OAI using the QSIT Part V was determined by the following multi-part Evaluation Form question: "Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) useful during your review? Yes __ No __ If yes, which tools were most useful and how were they helpful?" A total of 42 QSIT inspections were conducted during the Study. A Compliance Officer QSIT Evaluation Form was submitted for 41 of those inspections. Of those 41 inspections, 9 were classified OAI by the QSIT compliance officers using the QSIT Part V. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 5 (56 %) No 3 (33 %) Other 1 (11 %) *(1-No response)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # O4 (Activity 2)

COMPLIANCE OFFICER QSIT EVALUATION FORM question:

Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during your review? Yes __ NO __
If yes, which tools were most useful and how were they helpful?

TABULATION of RESPONSES
(Inspections Classified OAI Using the QSIT Part V)

Inspection Code	Yes	No	Other	Tools Most Useful and How They Were Helpful
1A1	X			Handbook
1A4	X			Book
1C3		X		
1C4	X			Book – helped me focus
1D1		X		
1D2	X			Narratives
1D3	X			Handbook narratives
2D3		X		
3B4			No response	
Total	5	3	1	